

guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(6) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information (42 U.S.C. 300aa-1 note).

(b) These officials may not further redelegate these authorities.

§ 5.201 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

(a) The following officials are authorized to perform all the functions of the Director, Center for Biologics Evaluation and Research (CBER) with regard to program authorities for their respective areas:

- (1) Deputy Directors, CBER.
- (2) Associate Directors, CBER.
- (3) Office Directors, CBER.
- (4) Division Directors, CBER.

(b) These officials may not further redelegate these authorities.

§ 5.202 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research are authorized to issue:

(1) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for biologics licenses under § 601.4(b) of this chapter.

(2) Notices of opportunity for a hearing on proposals to revoke biologics licenses under § 601.5(b) of this chapter.

(3) Notices of revocation, at the manufacturer's request, of biologics licenses under §§ 601.5(a) and 601.8 of this chapter.

(4) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

(5) Notice of biologics license suspensions under § 601.6 of this chapter.

(b) These officials may not further redelegate these authorities.

§ 5.203 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

(a) The following officials are authorized to issue licenses under section 351 of the PHS Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the PHS Act, and to revoke such licenses at the manufacturer's request:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

§ 5.204 Notification of release for distribution of biological products.

(a) The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 680.31) of this chapter:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER.

(3) The Director and Deputy Director, Division of Manufacturing and Product Quality, OCBQ, CBER.

(b) These officials may not further redelegate this authority.

Subpart E—Food and Cosmetics; Delegations of Authority

§ 5.300 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 409 and 721 of the act (21 U.S.C. 348 and 379e) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions

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on food additives, generally recognized as safe (GRAS) substances, and color additives that relate to the assigned functions of the respective Center:

(i) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Pre-market Approval, CFSAN.

(iv) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director, Deputy Director, and Director of Regulations and Policy, CFSAN are authorized to perform all the functions of the Commissioner under section 401 of the act (21 U.S.C. 341) regarding the issuance of proposed rulemaking (including notices of extension of, or reopening of, the comment period) pertaining to food standards.

(b)(1) The Director, Deputy Director, and Director of Regulations and Policy, CFSAN are authorized to perform all of the functions of the Commissioner under section 409 and 721 of the act (21 U.S.C. 348 and 379e) regarding the approval of the use of food additives under section 409(e) of the act (21 U.S.C. 348(e)) and the listing of color additives under section 721(d)(1) of the act (21 U.S.C. 379e) where the listing does not involve novel or controversial issues and does not involve any questions about the applicability of the Delaney Anti-Cancer Clause.

(2) The following officials are authorized to perform all of the functions of the Commissioner under section 401 of the act (21 U.S.C. 341) regarding the issuance of notices of temporary permits for foods varying from standards of identity under § 130.17 of this chapter:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(3) The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner regarding approvals of the use of food additives under section 409(e) of the act (21 U.S.C. 348(e)), where these approvals do

not involve novel or controversial issues, including any question about the applicability of the Delaney Anti-Cancer Clause.

(c)(1) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act (21 U.S.C. 348(c)(2)) or to color additive petitions under section 721e(d)(1) (21 U.S.C. 379e(d)(1)) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Pre-market Approval, CFSAN.

(iv) The Director, Division of Product Policy, Office of Premarket Approval, CFSAN.

(v) The Director, Division of Petition Control, Office of Premarket Approval, CFSAN.

(2) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act (21 U.S.C. 348(c)(2)) that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to certify batches of color additives under section 721 of the act (21 U.S.C. 379e):

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Cosmetics and Colors, CFSAN.

(e) The following officials are authorized to issue advance notices of proposed rulemaking pertaining to Codex Alimentarius food standards and notices terminating consideration of such standards when comments fail to support the desirability and need for proposing their adoption, under § 130.6 of this chapter:

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(f) The following officials are authorized to issue notices of proposed rulemaking and issue or amend regulations affirming GRAS status of food substances under §§ 170.35 or 570.35 of this chapter where the affirmations relate to the assigned functions of the respective Center and do not involve novel or controversial issues:

(1) The Director, Deputy Director, and Director of Regulations and Policy, CFSAN.

(2) The Director and Deputy Director, CVM.

(g)(1) The following officials are authorized to perform all of the functions of the Commissioner under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) regarding the issuance of decisions to grant or deny petitions for nutrient content claims and health claims that do not present controversial issues and regarding the issuance of any notices of proposed rulemaking that result from such action:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(2) The following officials are authorized to perform all of the functions of the Commissioner under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) regarding the issuing of letters of filing in response to petitions for nutrient content claims and health claims:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(h) The following officials are authorized to issue letters concerning substances determined to be below the “threshold of regulation” under § 170.39 of this chapter:

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(4) The Directors of the Divisions of Petition Control and Product Policy, Office of Premarket Approval, CFSAN.

(i) The following officials are authorized to perform all of the functions of the Commissioner under section 409(h) of the act (21 U.S.C. 348(h)), excluding the duties to set out in section 409(h)(5) of the act (21 U.S.C. 348(h)(5)), regarding premarket notification of food-contact substances:

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(j) These officials may not further redelegate these authorities.

§5.301 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.

(a) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN), the Director, Office of Field Programs, CFSAN, and the Director, Division of Enforcement and Programs, Office of Field Programs, CFSAN, are authorized to issue initial emergency permit orders under §108.5 of this chapter.

(b) The following officials are authorized to issue notices of confirmation of effective date of final regulations on food matters issued under section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)):

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(4) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(5) The Director, Office of Seafood, CFSAN.

(6) The Director, Office of Field Programs, CFSAN.

(7) The Director, Office of Premarket Approval, CFSAN.

(c) These officials may not further redelegate these authorities.